## WE CLAIM:

1 1. A controlled release pharmaceutical composition of tamsulosin, the composition comprising:

- 3 (a) a spheroid core comprising:
- 4 i. tamsulosin,
- 5 ii. about 10% to about 45% w/w of a spheronizing agent,
- 6 iii. one or more of rate controlling polymers, and;
- 7 (b) an enteric coating over the spheroid core.
- 1 2. The composition of claim 1, wherein the tamsulosin comprises free base,
- 2 pharmaceutically acceptable salts and isomers of tamsulosin.
- 1 3. The composition of claim 2, wherein the pharmaceutically acceptable salts of
- 2 tamsulosin comprise one or more of hydrochloride, hydroiodide, hydrobromide,
- and hydrogen fumarate..
- 1 4. The composition of claim 3, wherein the pharmaceutically acceptable salt of tamsulosin is a hydrochloride.
- 1 5. The composition of claim 1, wherein the composition comprises a concentration from about 0.03% to about 0.33% by weight of tamsulosin.
- 1 6. The composition of claim 1, wherein the spheronizing agent is microcrystalline cellulose.
- 1 7. The composition of claim 1, wherein the rate controlling polymer comprises one or
- 2 more of enteric polymers, water insoluble polymers, water soluble polymers,
- alkaline metal salts of a higher fatty acid, waxes, and mixtures thereof.
- 1 8. The composition of claim 1, wherein the composition comprises from about 20%
- 2 to about 90% by weight of rate controlling polymers.
- 1 9. The composition of claim 7, wherein the enteric polymer comprises one or more of
- 2 hydroxylpropylmethyl cellulose phthalate, cellulose acetate phthalate, methacrylic
- acid and ethyl acrylate copolymer.
- 1 10. The composition of claim 9, wherein the enteric polymer comprises one or more of methacrylic acid and ethyl acrylate copolymer.

1 11.	The composition of claim	7, wherein the wax	comprises one or more of
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- 2 hydrogenated vegetable oils, esters of long chain fatty acids, long chain fatty acids,
- 3 and mixtures thereof.
- 1 12. The composition of claim 11, wherein the wax is glyceryl monostearate.
- 1 13. The composition according to claim 11, wherein the wax is stearic acid.
- 1 14. The composition of claim 7, wherein the water soluble polymer comprises one or
- 2 more of polyvinylpyrrolidone, hydroxypropyl cellulose, carboxymethylcellulose
- 3 sodium, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, methyl cellulose,
- 4 and mixtures thereof.
- 1 15. The composition of claim 7, wherein the water insoluble polymer comprises one or
- 2 more of ethyl cellulose, cellulose acetate, methacrylic acid-acrylic acid copolymers
- with quaternary ammonium groups, and mixtures thereof.
- 1 16. The composition of claim 7, wherein the alkaline metal salts of higher fatty acid
- 2 comprise one or more of magnesium stearate, zinc stearate, calcium stearate, and
- 3 mixtures thereof.
- 1 17. The composition of claim 16, wherein the alkaline metal salt of higher fatty acid is
- 2 magnesium stearate.
- 1 18. The composition of claim 1, wherein the spheroid core includes one or more of
- 2 pharmaceutically acceptable excipients.
- 3 19. The composition of claim 18, wherein the pharmaceutically acceptable excipients
- 4 include plasticizers, diluents, colorants, and flavoring agents.
- 1 20. The composition of claim 1, wherein the enteric coating layer comprises one or
- 2 more of hydroxypropyl methylcellulose phthalate, polyvinyl phthalate, cellulose
- acetate phthalate, copolymers of acrylic and methacrylic acid, and mixtures
- 4 thereof.
- 1 21. The composition of claim 20, wherein the enteric coating includes one or more of
- 2 alkalizing agents, plasticizer, tack-modifiers and opacifiers.
- 1 22. The composition of claim 1, wherein the composition comprises capsules, sachets,
- 2 and tablets.

1 2	23.	A process for the preparation of a controlled release pharmaceutical composition of tamsulosin, the process comprising:	
3 4		(a) granulating tamsulosin, spheronizing agent and one or more rate controlling polymers to obtain a granulating mixture,	
5		(b) extruding the granulated mixture to obtain extrudates,	
6		(c) spheronizing the extrudates to obtain spherical cores,	
7		(d) drying the spheroid cores; and	
8		(e) coating the spheroid cores with an enteric polymer.	
1 2	24.	The process of claim 24, wherein the tamsulosin comprises free base, pharmaceutically acceptable salts and isomers of tamsulosin.	
1	25.	The process of claim 24, wherein the pharmaceutically acceptable salts of	
2		tamsulosin comprise hydrochloride, hydroiodide, hydrobromide, and hydrogen	
3		fumarate.	
1	26.	The process of claim 25, wherein the pharmaceutically acceptable salt of	
2		tamsulosin is a hydrochloride.	
1	27.	The process of claim 23, wherein the pharmaceutical composition comprises a	
2		concentration of about 0.03% to about 0.33% by weight of tamsulosin.	
1 2	28.	The process according to claim 23, wherein the spheronizing agent is microcrystalline cellulose.	
1	29.	The process of claim 23, wherein the rate controlling polymer comprises one or	
2		more of enteric polymers, water insoluble polymers, water-soluble polymers,	
3		alkaline metal salts of a higher fatty acid, waxes, and mixtures thereof.	
1 2	30.	The process of claim 23, wherein the pharmaceutical composition comprises a concentration of about 20% to about 90% by weight of rate controlling polymers.	
1	31.	The process of claim 29, wherein the enteric polymer comprises one or more of	
2		hydroxylpropylmethyl cellulose phthalate, cellulose acetate phthalate, methacrylic acid and ethyl acrylate copolymer.	
1	32.	The process of claim 31, wherein the enteric polymer comprises one or more of	
2		methacrylic acid and ethyl acrylate copolymer.	

1 33. The process of claim 29, wherein the wax comprises one or more of hydrogenated

- 2 vegetable oils, esters of long chain fatty acids, long chain fatty acids, and mixtures
- 3 thereof.
- 1 34. The process of claim 33, wherein the wax is glyceryl monostearate.
- 1 35. The process of claim 33, wherein the wax is stearic acid.
- 1 36. The process of claim 29, wherein the water soluble polymer comprises one or more
- of polyvinylpyrrolidone, hydroxypropyl cellulose, carboxymethylcellulose sodium,
- 3 hydroxypropylmethyl cellulose, hydroxyethyl cellulose, methyl cellulose, and
- 4 mixtures thereof.
- 1 37. The process of claim 29, wherein the water insoluble polymer comprises one or
- 2 more of ethyl cellulose, cellulose acetate, methacrylic acid-acrylic acid copolymers
- 3 with quaternary ammonium groups, and mixtures thereof.
- 1 38. The process of claim 29, wherein the alkaline metal salts of higher fatty acids
- 2 comprise one or more of magnesium stearate, zinc stearate, calcium stearate, and
- 3 mixtures thereof.
- 1 39. The process of claim 38, wherein the alkaline metal salt of higher fatty acid is
- 2 magnesium stearate.
- 1 40. The process of claim 23, wherein the spheroid core includes one or more of
- 2 pharmaceutically acceptable excipients
- 1 41. The process of claim 40, wherein the pharmaceutically acceptable excipient
- 2 comprises one or more of plasticizers, diluents, colorants or flavoring agents.
- 1 42. The process of claim 23, wherein the enteric coating comprises enteric polymers.
- 1 43. The process of claim 42, wherein the enteric polymer comprises one or more of
- 2 hydroxypropyl methylcellulose phthalate, polyvinyl phthalate, cellulose acetate
- phthalate, copolymers of acrylic and methacrylic acid, and mixtures thereof.
- 1 44. The process of claim 42, wherein the enteric coating comprises one or more of
- 2 alkalizing agents, plasticizer, tack-modifiers and opacifiers.
- 1 45. The process of claim 23, wherein the composition is filled into capsules, sachets,

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2 or compressed into tablets.

1 46. A process for the preparation of a controlled release pharmaceutical composition of tamsulosin, the process comprising:

(a) granulating tamsulosin and spheronizing agent with dispersion of one controlled release pharmaceutical composition of tamsulosin, the process comprising:

- (a) granulating tamsulosin and spheronizing agent with dispersion of one or
   more of rate controlling polymers to obtain granulates,
- 5 (b) extruding the granulates to form extrudates using extruder,
- 6 (c) spheronizing the extrudates until spherical cores are formed; and
- 7 (d) coating the spherical cores with an enteric polymer.
- 1 47. The process of claim 46, wherein the tamsulosin comprises free base,
- 2 pharmaceutically acceptable salts and isomers of tamsulosin.
- 1 48. The process of claim 47, wherein the pharmaceutically acceptable salts of
- 2 tamsulosin comprise hydrochloride, hydroiodide, hydrobromide, and hydrogen
- 3 fumarate.
- 1 49. The process of claim 48, wherein the pharmaceutically acceptable salt of tamsulosin is a hydrochloride.
- The process of claim 46, wherein the pharmaceutical composition comprises a concentration of about 0.03% to about 0.33% by weight of tamsulosin.
- 1 51. The process of claim 46, wherein the spheronizing agent is microcrystalline cellulose.
- 1 52. The process of claim 46, wherein the rate controlling polymer comprises one or more of enteric polymers, water insoluble polymers, water-soluble polymers,
- alkaline metal salts of a higher fatty acid, waxes, and mixtures thereof.
- 1 53. The process of claim 46, wherein the pharmaceutical composition comprises a concentration of about 20% to about 90% by weight of rate controlling polymers.
- 1 54. The process of claim 52, wherein the enteric polymer comprises one or more of hydroxylpropylmethyl cellulose phthalate, cellulose acetate phthalate, methacrylic
- 3 acid and ethyl acrylate copolymer.
- 1 55. The process of claim 54, wherein the enteric polymer comprises one or more of methacrylic acid and ethyl acrylate copolymer.

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1 56. The process of claim 52, wherein the wax comprises one or more of hydrogenated

- vegetable oils, esters of long chain fatty acids, long chain fatty acids, and mixtures
- 3 thereof.
- 1 57. The process of claim 56, wherein the wax is glyceryl monostearate.
- 1 58. The process of claim 56, wherein the wax is stearic acid.
- 1 59. The process of claim 52, wherein the water soluble polymer comprises one or more
- 2 of polyvinylpyrrolidone, hydroxypropyl cellulose, carboxymethylcellulose sodium,
- 3 hydroxypropylmethyl cellulose, hydroxyethyl cellulose, methyl cellulose, and
- 4 mixtures thereof.
- 1 60. The process of claim 52, wherein the water insoluble polymer comprises one or
- 2 more of ethyl cellulose, cellulose acetate, methacrylic acid-acrylic acid copolymers
- with quaternary ammonium groups, and mixtures thereof.
- 1 61. The process of claim 52, wherein the alkaline metal salts of higher fatty acids
- 2 comprise one or more of magnesium stearate, zinc stearate, calcium stearate, and
- 3 mixtures thereof.
- 1 62. The process of claim 61, wherein the alkaline metal salt of higher fatty acid is
- 2 magnesium stearate.
- 1 63. The process of claim 46, wherein the spheroid core includes one or more of
- 2 pharmaceutically acceptable excipients
- 1 64. The process of claim 63, wherein the pharmaceutically acceptable excipient
- 2 includes one or more of plasticizers, diluents, colorants, and flavoring agents.
- 1 65. The process of claim 46, wherein the enteric coating comprises enteric polymers.
- 1 66. The process of claim 65, wherein the enteric polymer comprises one or more of
- 2 hydroxypropyl methylcellulose phthalate, polyvinyl phthalate, cellulose acetate
- phthalate, copolymers of acrylic and methacrylic acid, and mixtures thereof.
- 1 67. The process of claim 46, wherein the enteric coating comprises one or more of
- 2 alkalizing agents, plasticizer, tack-modifiers and opacifiers.
- 1 68. The process of claim 46, wherein the composition is filled into capsules, sachets,
- 2 or compressed into tablets.

